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TITLE: Comparing Virtual Reality Exposure Therapy to Prolonged Exposure in the treatment of Soldiers with PTSD

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14. ABSTRACT

This randomized, single blind study is evaluating the efficacy of virtual reality exposure therapy (VRET) by comparing it to prolonged exposure therapy (PE) and a waitlist (WL) group in the treatment of post-traumatic stress disorder (PTSD) in active duty (AD) Soldiers with combat-related trauma. During the first year, the study team developed the infrastructure to implement the trial including personnel hiring and training, process development to identify, screen, and enroll participants, completion of study-related VR Iraq scenarios, and research protocol development. During the second year, recruitment and enrollment of soldiers for study participation began, and by the end of year two 145 referrals for treatment had been received, 84 subjects consented to study participation and 45 met all of the inclusion and none of the exclusion criteria and were randomized to treatment. During the third year, recruitment and enrollment of participants continued with an additional 100 referrals for treatment received, 72 subjects consented to study participation and 39 randomized to one of the 3 arms of the study, VR, PE or WL. During year 4, the period covered in this report, 119 referrals have been received, 72 participants consented to study participation and 43 met all the inclusion criteria and none of the exclusion criteria and were randomized.

15. SUBJECT TERMS
PTSD, virtual reality exposure therapy (VRET), prolonged exposure therapy (PE)

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INTRODUCTION.

This randomized, single blind study is evaluating the efficacy of virtual reality exposure therapy (VRET) by comparing it to prolonged exposure therapy (PE) and a waitlist (WL) group in the treatment of post-traumatic stress disorder (PTSD) in active duty (AD) Soldiers with combat-related trauma. The study will test the general hypotheses that 10 sessions of VRET will successfully treat PTSD, therapeutically affect levels of physiological arousal, and significantly reduce perceptions of stigma toward seeking behavioral health services. Soldiers returning from deployments to Iraq who are diagnosed with combat-related PTSD following administration of the Clinician-Administered PTSD Scale (CAPS) will be randomized to one of three groups: 1) PE; 2) VRET; or 3) WL. Soldiers will undergo clinical assessments at baseline and after 5 and 10 treatment sessions. Outcome measures will also be collected at 12 and 26 weeks post-treatment. Physiological arousal, patient satisfaction with treatment, and stigma toward seeking behavioral health services will also be explored.

BODY.

During this reporting period the study team has continued recruitment, enrollment and follow-up of study participants throughout the year. Comprehensive advertising campaigns, including clinic briefings, flyers, posters and websites have continued to draw potential participants. The consultant team provides ongoing treatment fidelity evaluations and the research team is conducting continuous inter-rater reliability assessments.

Initial recruitment for this study began in May 2009. Total study numbers to date include 364 referrals, 228 subjects consented to study participation and 127 meeting all of the inclusion and none of the exclusion criteria and randomized to treatment. Of the 84 subjects randomized to either active treatment group, 5 are currently “in-treatment” phase (treatment sessions 1-10), 11 are waiting for 12 or 26 week follow-up assessments. 19 subjects have completed study participation through 26 week follow-up. 49 subjects have dropped from study participation prior to completing the 26 week follow-up, either by withdrawing consent or becoming lost to follow-up. Of these 49 drop outs, 13 completed the active treatment phase and post-treatment assessment, 33 subjects withdrew prior to completing 10 treatment sessions/post-assessment, and 3 subjects were withdrawn by the study team during the active phase of the study.

During this reporting period 119 referrals for treatment were received, 72 subjects consented to study participation and 43 of those met all of the inclusion and none of the exclusion criteria and were randomized to treatment. Of the 43 subjects randomized to the ‘waitlist’ (WL) condition, 36 subjects have completed study participation through the post-assessment visit, and 5 dropped from study participation, either by withdrawing consent or becoming lost to follow-up. Two are currently active in the WL group.

Ongoing recording and review of sessions has been implemented in order to ensure treatment fidelity of 15% of treatment sessions.

<u>Modification</u>

An amendment to add an additional recruitment site (Ft. Bragg, NC) and defer oversight of study approval from Womack Army Medical Center (WAMC) to Madigan Army Medical

Center (MAMC) IRB's was approved by both IRB's. Site-specific protocol documents, Informed Consent Forms and advertisement materials were submitted in subsequent amendments and approved. The report of progress for this study site is available from grant # W81XWH-11-2-0007.

Amendments to add study staff (new recruitment site and existing site) and update recruitment websites were submitted and approved during this reporting period. The DMRN cover sheet has been updated and approved.

Challenges

Challenges previously identified continued during this reporting period and include subject recruitment and retention. Despite continuing PI and sub-I clinic updates around the installation, recruitment has remained slower than desired. Retention in treatment groups has also been problematic. We previously added the "Intent to Return" measure at each session to improve identification of barriers to care and problem solving. However, of the total enrolled sample who had the opportunity to complete study participation (to include 26-week follow-up), nearly 50% attrition has been observed. Although this may not be surprising for a highly mobile active duty population, it will negatively impact our observation of the persistence of treatment effects. The investigators are exploring options for reducing missing data, including the possibility of amending the protocol to include phone follow-up assessment of symptoms and voluntary coordination with Command to increase support for study participation.

KEY RESEARCH ACCOMPLISHMENTS.

Administrative and logistical matters.

a). Personnel.

1) Study staff continued enrollment, assessment, treatment and all other study-related activities.

b) Materials, supplies and consumables.

1) Supplies and materials for study requirements continue to be coordinated in support of human subject enrollment.

c) Institutional Review Board.

1) Annual Continuing review conducted by the MAMC IRB was approved 22MAY2012.

REPORTABLE OUTCOMES.

None

CONCLUSION.

None

REFERENCES.

None

APPENDICIES.
None